REMARKS

THE AMENDMENT TO CLAIM 51

Claim 51 has been amended to correct an obvious typographical error. No new matter is added to the application with the change to claim 51.

THE REFERENCES CITED IN THE SPECIFICATION

At page 2 of the Office Action, the Examiner states that the references cited in the specification are not a proper Information Disclosure Statement under 37 C.F.R. § 1.98. Applicants submit that all the references cited in the Background of the Invention were cited in the IDS filed with the application on January 27, 2004. All references cited in the specification that were not submitted in the IDS were cited for purposes of illustration only and as such, have no bearing on the patentability of the claimed invention and therefore, are not proper references for submission in an IDS.

OBJECTION TO THE SPECIFICATION

Pursuant to the Examiner's request, paragraph 0028 of the Brief Description of the Drawings has been amended to specify that Figure 3 is actually Figure 3a and 3b. No new matter has been added to the application with this change.

THE SPECIES ELECTION REQUIREMENT

Applicants acknowledge the Examiner's extension of the species election requirement of December 20, 2004, to include all of the non-elected claims.

THE DOUBLE-PATENTING REJECTION OVER USPN 5,580,923

Claims 1-3, 16, 21, and 22 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 18-24 of U.S. Patent No. 5,580,923 ("the '923 Patent"). This rejection is respectfully traversed.

Under the judicially-created doctrine of obviousness double patenting is a nonstatutory-type double patenting rejection based on a judicially created doctrine grounded in public policy that is intended to prevent prolongation of the patent term by prohibiting claims in a second patent no patentably distinguishable from claims in a first patent.

As recited in independent claim 1, the claimed invention relates to a method for augmenting soft or hard tissue within a mammalian body, comprising (a) providing a first crosslinkable component having m nucleophilic groups, wherein $m \geq 2$; (b) providing a second crosslinkable component having n

electrophilic groups capable of reaction with the m nucleophilic groups to form covalent bonds, wherein n ≥ 2 and $m + n \geq 5$; (c) applying the first and second crosslinkable components to the tissue; and (d) allowing the first and second crosslinkable components to crosslink *in situ*, wherein the first and second crosslinkable components are biocompatible, synthetic, and nonimmunogenic.

Claims 16 and 19 recite that where the m nucleophilic groups are primary amino groups, the n electrophilic are selected from the group consisting of succinimidyl ester, sulfosuccinimidyl ester, maleimido, epoxy, isocyanato, thioisocyanato, and ethenesulfonyl, and claims 21 and 22 recite that where the m nucleophilic groups are sulfhydryl groups, the n electrophilic groups are sulfhydryl-reactive groups selected so as to form a thioester, thioether, or disulfide linkage upon reaction with the sulfhydryl groups.

The '923 Patent is described at paragraph 0007 of the specification of the instant application. There, the application explains that the '923 Patent describes a composition useful in the prevention of surgical adhesions comprising a substrate material and an anti-adhesion binding agent, wherein the substrate material preferably comprises collagen and the binding agent preferably comprises at least one tissue-reactive functional group and at least one substrate-reactive functional group.

Independent claim 18 of the '923 Patent relates to an anti-adhesion device for treatment of receptive tissue, said device comprising at least one layer of substrate material covalently bonded to an anti-adhesion binding agent, wherein said anti-adhesion agent further comprises a tissue-selective functional group. Claims 19-24 depend from claim 18. Claim 20 recites that the substrate material is collagen; claim 23 recites that the binding agent comprises a derivative of polyethylene glycol ("PEG"); and claims 21 and 22 recite that the tissue-selective functional groups are sulfhydryl-selective functional groups and amine-comprising functional groups, respectively. Claim 24 recites a method for preventing the formation of an adhesion by covalently bonding the anti-adhesion device of claim 18.

At paragraph 0024 of the instant application, the differences between the invention of the '923 Patent and that of the present invention are addressed; there, is it noted that because the compositions of the present invention are not subject to enzymatic cleavage by matrix metalloproteinases, such as collagenases, the compositions of the present invention are not readily degradable *in vivo* and, as such, are expected to have greater long-term persistence *in vivo* than prior art collagen compositions.

As is clear from the claims set forth above, the claimed invention is directed to a method of augmenting tissue through the use of two crosslinkable components that are applied to the tissue and that crosslink *in situ*, wherein the crosslinkable components are comprised of primary amino groups and amino-reactive groups or sulfhydryl groups and sulfhydryl reactive groups. By contrast, the '923 Patent is directed to a device comprised of a substrate material, i.e., collagen, bonded to a PEG derivative.

The Examiner asserts that claim 24 of the '923 Patent is encompassed in the method of the claimed invention because it recites a method of formation of adhesion with polymeric material of the type of the claimed invention. The Examiner's analysis is not correct for the reasons that follow.

As a preliminary matter, claim 24 of the '923 Patent is ***not*** directed to a method of formation of adhesion; rather, it is a method for ***preventing*** the formation of adhesions. As is well known in the medical arts, an adhesion is a condition that results when bodily tissues that are usually separate grow together; thus, it follows that anti-adhesion is a process of keeping tissues that do not belong together from growing together. In light of the foregoing, it follows that the purpose of the method of the claimed invention and the method of claim 24 of the '923 Patent are completely different. Whereas the claimed method is designed to enhance the formation of desired tissue, the method of the '923 Patent is designed to prevent the formation of undesired tissue.

In addition to the foregoing, while the device of the '923 Patent is designed to adhere covalently to a collagen substrate, the compositions of the claimed invention are designed specifically to not require collagen.

Because the '923 Patent does ***not*** teach or suggest that the device disclosed therein may be produced without collagen and may be used to augment tissue, it follows that the device and method of the '923 Patent does not render the claimed invention obvious. For the foregoing reasons, applicants respectfully request reconsideration and withdrawal of this rejection.

THE DOUBLE-PATENTING REJECTION OVER USPN 5,752,974

Claims 1-25, 29, 33-51, 53-59, 67, and 68 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-48 of U.S. Patent No. 5,752,974 ("the '974 Patent"). In response, applicants are submitting a terminal disclaimer over the '974 Patent. Applicants would like to make it of record that the terminal disclaimer over the '974 Patent is made solely for the purpose of expediting the prosecution of this case and that the submission of the terminal disclaimer is not intended to represent applicants' acquiescence in the substance of the Examiner's rejection.

THE DOUBLE-PATENTING REJECTION OVER USPN 6,166,130

Claims 1-68 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-4 and 7-13 of U.S. Patent No. 6,166,130 ("the '130 Patent"). In response, applicants are submitting a terminal disclaimer over the '130 Patent. Applicants would like to make it of record that the terminal disclaimer over the '130 Patent is made solely for the purpose of expediting the

prosecution of this case and that the submission of the terminal disclaimer is not intended to represent applicants' acquiescence in the substance of the Examiner's rejection.

THE DOUBLE-PATENTING REJECTION OVER USPN 6,312,725

Claims 1, 19-22, and 35 stand rejected under the judicially created doctrine of obviousness-type double patenting over claim 17 of U.S. Patent No. 6,312,725 ("the '725 Patent"). In response, applicants are submitting a terminal disclaimer over the '725 Patent. Applicants would like to make it of record that the terminal disclaimer over the '725 Patent is made solely for the purpose of expediting the prosecution of this case and that the submission of the terminal disclaimer is not intended to represent applicants' acquiescence in the substance of the Examiner's rejection.

THE DOUBLE-PATENTING REJECTION OVER USPN 6,495,127

Claims 1-22, 29, and 35-56 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 1, 32-44, 48, 49, 67-72, and 76-81 of U.S. Patent No. 6,495,127 ("the '127 Patent"). In response, applicants are submitting a terminal disclaimer over the '127 Patent. Applicants would like to make it of record that the terminal disclaimer over the '127 Patent is made solely for the purpose of expediting the prosecution of this case and that the submission of the terminal disclaimer is not intended to represent applicants' acquiescence in the substance of the Examiner's rejection.

THE DOUBLE-PATENTING REJECTION OVER USPN 6,833,408

Claims 1-68 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 153 of U.S. Patent No. 6,833,408 ("the '408 Patent"). In response, applicants are submitting a terminal disclaimer over he '408 Patent. Applicants would like to make it of record that the terminal disclaimer over he '408 Patent is made solely for the purpose of expediting the prosecution of this case and that the submission of the terminal disclaimer is not intended to represent applicants' acquiescence in the substance of the Examiner's rejection.

THE DOUBLE-PATENTING REJECTION OVER U.S. PATENT APPLICATION SERIAL NO. 10/766,095

Claims 1-68 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-32 of copending U.S. Patent Application Serial No. 10/766,095 ("the '095 Application," published as United States Patent Publication No. 2004/0186231 A1).

As a preliminary matter, applicants would like to emphasize that this rejection is a provisional obviousness-type double-patenting rejection because the claims of the '095 Application are not yet issued. *See*, MPEP § 804, p.108-18 (8th ed., Aug. 2001, rev. May 2004). Notwithstanding the foregoing and solely for purposes of expediting the prosecution of this application, applicants are submitting a terminal disclaimer over the '095 Application. Applicants would like to make it of record that the terminal disclaimer over the '095 Application is not intended to represent applicants' acquiescence in the substance of the Examiner's rejection.

THE ENABLEMENT REJECTION

Claims 35-68 stand rejected under 35 U.S.C. § 112, first paragraph, as not enabling for the prevention of the formation of adhesions following surgery. This rejection is respectfully traversed.

The *prima facie* case is a procedural tool which, as used in patent examination, means not only that the evidence of the prior art would reasonably allow the conclusion the Examiner seeks, but also that the prior art compels such a conclusion if the applicant produces no evidence or argument to rebut it. *In re Spada,* 911 F.2d 705 (Fed. Cir. 1990). If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more, the applicant is entitled to a grant of the patent. *In re Oetiker,* 977 F.2d 1443 (Fed. Cir. 1992).

The enablement requirement as set forth at 35 U.S.C. § 112, first paragraph, provides that the specification shall describe the "manner and process of making and using [the invention], in such clear and concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use [the invention]. 35 U.S.C. § 112, first paragraph (2000).

At page 6 of the Office Action, the Examiner asserts that the specification is not enabling for the prevention of adhesions because the specification does not provide sufficient and adequate guidance to practice the art. Applicants disagree. Paragraphs 0181 to 0184 of the application describes in detail the use of the claimed composition for the prevention of adhesions. There, it is explained that the tissues at the surgical site are coated with the compositions of the claimed invention and that once the tissues are coated, they will not stick to one another.

Citing case law, the Examiner questions the rate of success of administering the polymer to the site following surgery and in so doing, states that the scope of enablement is not commensurate with the scope of protection sought. Applicants once again disagree with the Examiner this time on the grounds that the enablement requirement does not have a "rate of success" requirement, it only requires that the specification teach the ordinary artisan "how to make" and "how to use" the invention. *See*, *In re Moore*, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971) (cited by the Examiner). It is unarguable that

the specification of the instant application teaches the ordinary artisan in great detail how to make the claimed composition; As noted above, paragraphs 0181 to 0184 teach the ordinary artisan how to use the compositions for the prevention of adhesions during surgery.

Applicants have reviewed the case law cited by the Examiner and do not find any guidance in the case law to support the Examiner's position that the specification is not enabling for the prevention of adhesions.

In *Steel Corp. v. Sollac*, 233 F.3d 1234, 1244 , 68 USPQ2d 1280, 1287 (Fed. Cir. 2003), the claims at issue were directed to steel strips containing either Type 1 or Type 2 aluminum coatings that wet well. The Federal Circuit held that the claims were undoubtedly enabled for the Type 2 aluminum coating, but were not enabling for the Type 1 aluminum coating because the specification expressly taught that the Type 1 aluminum coating would not wet well. In the instant case, applicants are not claiming anything that is not expressly taught in the specification; rather, claims 35-68 of the instant application are fully supported by the disclosure of the compositions set forth throughout the application as well as the use of the compositions for the method of the claimed invention as disclosed at paragraphs 0181-0184 of the specification. In light of the foregoing, applicants submit that *Steel Corp.* does not support the Examiner's position that the claims are not enabled.

In *In re Moore*, the claims at issue were directed to fluorinated products. The Board of Patent Appeals, reading process parameters into the claims, attempted to limit the scope of the fluorinated products. Expressing disbelief at the approach taken by the Board, the CCPA reversed the Board's finding that the claims were not enabling for all fluorinated products covered under the claims. In so doing, the CCPA emphasized that the enablement provision of 35 U.S.C. § 112, first paragraph, requires only that the specification teach the ordinary artisan "how to make" and "how to use" the claimed invention. As noted above, the specification of the instant application successfully accomplishes both of these requirements of the enablement provision of the patent statute. Thus, *In re Moore* actually supports the enablement of the claims of the instant application.

In *Plant Genetics Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1339, 65 USPQ2d 1452, 1455 (Fed. Cir. 2003), the patentee attempted to convince the Federal Circuit that it was entitled to a broad scope of coverage and a lower standard of enablement because the claims at issue recited a pioneering invention. The Federal Circuit dismissed such arguments as unsupported by precedent and irrelevant to the enablement mandates of 35 U.S.C. § 112, first paragraph. *Plant Genetics*, 65 USPQ2d at 1457. In the instant case, applicants are not asserting that the claimed invention is entitled to any standard over and beyond that set forth in the patent statute; rather, applicants are only traversing the Examiner's rejection the grounds that the claimed invention properly teaches the ordinary artisan how to make the

claimed compositions and how to use them for the prevention of adhesions. In light of the foregoing, applicants submit that *Plant Genetics* also does not support the Examiner's position that the claims of the instant application are not enabled.

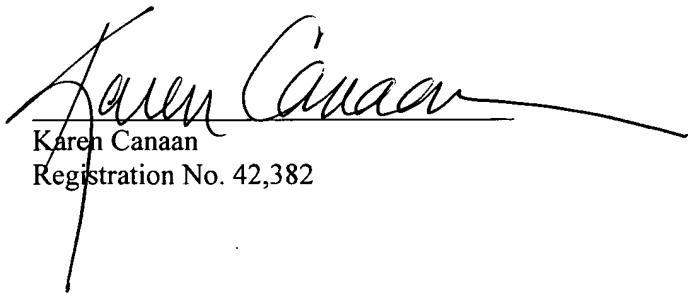
Because the Examiner has not provided applicants with any case law to substantiate the Examiner's assertion that a rate of success is a requirement of the enablement provision of the patent statute, applicants submit that the Examiner has not established a *prima facie* case of enablement. In light of the foregoing, applicants respectfully request withdrawal of this rejection.

CONCLUSION

Each of the Examiner's rejections in the Office Action under reply has been addressed and overcome; accordingly, applicants respectfully request withdrawal of all objections to the application and claim rejections and passage of this application to issue.

If the Examiner has any questions regarding this Amendment that may be addressed by way of a telephone call or e-mail correspondence, she is encouraged to contact the undersigned at 650-251-7713 or canaan@reedpatent.com.

Respectfully submitted,

By: 

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